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*LIMITED TO MATTERS
AND PROCEEDINGS BEFORE
FEDERAL COURTS & AGENCIES
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November 21, 2001

WRITER'S DIRECT NUMBER:
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Commissioner for Patents
Washington, D.C. 20231

Attn: Art Unit 1633

Re: U.S. Utility Patent Application
Appl. No. 09/557,907; Filed: April 21, 2000
For: **Treatment of Cancer Using Cytokine-Expressing
Polynucleotides and Compositions Therefor**
Inventors: Horton *et al.*
Our Ref: 1530.0060004/EKS/EJH

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction Requirement; and
2. One (1) return postcard.

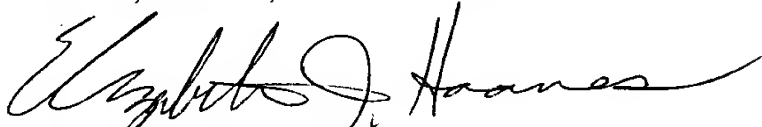
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
November 21, 2001
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes". The signature is fluid and cursive, with the first name "Elizabeth" written in a larger, more prominent script than the last name "Haanes".

Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

EJH/PAC/nef
Enclosures

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HORTON, *et al.*

Appl. No. 09/557,907

Filed: April 21, 2000

For: **Treatment of Cancer Using
Cytokine-Expressing
Polynucleotides and Compositions
Therefor**

Confirmation No. N/A

Art Unit: 1633

Examiner: Wilson, M.

Atty. Docket: 1530.0060004/EKS/EJH

Reply To Restriction Requirement

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated October 22, 2001 (P.T.O. File Wrapper Paper No. 11), requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect, with traverse, to prosecute the invention within Group I, represented by claims 1-35, 38-50, 66-75 and 77-87. With respect to Group II, Applicants believe that the inclusive claims should be claims 36, 37, 52-56, 58-64, 89-94 and 96-103, and should not include claims 66-87. If the Examiner disagrees, clarification is respectfully requested. Applicants reserve the right to pursue the non-elected claims in related applications.

With respect to the Examiner's further division of the claims in the previously elected group into two groups and the reasons stated therefor, Applicants respectfully traverse. Groups I and II are related as between polynucleotide-containing pharmaceutical compositions (Group I), and polynucleotide-containing pharmaceutical compositions comprising sodium phosphate dissolved in an aqueous solution at a molar concentration

ranging from about 20 mM to about 300 mM (Group II). Even assuming, *arguendo*, that Groups I and II represent distinct or independent inventions, Applicants submit that to search and examine the subject matter of Groups I and II together would not be a serious burden on the Examiner. Groups I and II are both related to the delivery of polynucleotides into tissue. Publications disclosing the methods of Group I would largely overlap with publications disclosing the methods of Group II. The compositions of both Groups I and II share common structural features which are essential to their functioning in the delivery, uptake, and expression of polynucleotides *in vivo*. It is a simple matter for the Examiner to search and examine publications disclosing methods and compositions of both groups. The M.P.E.P. § 803 (Eighth Edition, Rev. August, 2001) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

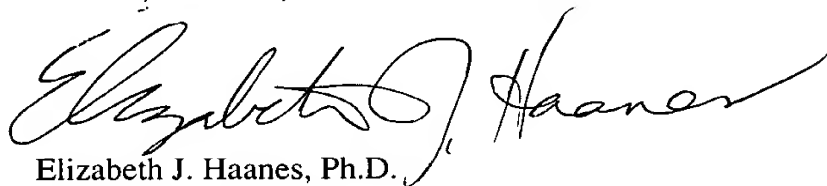
Thus, in view of the M.P.E.P. § 803, Applicants respectfully request that the claims of Groups I and II be searched and examined in the captioned application. Applicants retain the right to petition from the Restriction Requirement under 37 C.F.R. § 1.144. Reconsideration and withdrawal of the Restriction Requirement, and examination and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions

of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes". The signature is fluid and cursive, with the first name "Elizabeth" and last name "Haanes" clearly distinguishable.

Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

Date: November 21, 2001

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